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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,191	02/27/2007	Shuibing Chen	014740-001020US	4061

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
12/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,191	CHEN ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9-14-09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 9-14-09 has been entered. Claim 27 has been amended. Claims 20-27 and the Formula 1 species from 2,6-disubstituted purines are pending and under consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20-27 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention and is repeated for the reasons set forth in the preceding Official action mailed 3-13-09. Applicant's arguments filed 9-14-09 have been fully considered but they are not persuasive.

Applicants argue that no undue experimentation is required and the claims are enabled although extensive experimentation is required. The specification provides detailed description of the process for myoblast cells and these examples unequivocally demonstrate that the claimed method can be used to identify compounds that induce dedifferentiation of lineage committed mammalian cells into multipotent stem cells. Applicants argue that the cited references concern pluripotent stem cells rather than multipotent stem cells (amendment, p. 7-8). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 3-13-09.

The claims encompass inducing dedifferentiation of any lineage committed mammalian cell to multipotent stem cell, identification of the multiple stem cell, differentiation of said multipotent stem cell into various cell types and identification of said cell types. The mammalian cell can be any cell type, such as epithelial cell, endothelial cell, fibroblast, skeletal muscle cell, smooth muscle cell, glial cell, and neuronal cell etc., and the cell can be derived from numerous different mammals, such as mice, rats, other rodents, humans, monkey, baboons, chimpanzee, other primates, horse, cows, pigs, sheep, dogs, cats, whales, and other mammals etc. The specification fails to provide adequate guidance and evidence for how to identity multipotent stem cells of different cell types derived from numerous different mammals, and how to identify numerous different cell types differentiated from said multipotent stem cells derived from various mammals. The cited references Allegrucci, Sato, Rao and Abeyta discusses complexity of cell markers in difference embryonic stem cells, they imply the complexity of cells markers among different multipotent stem cells. Further, the cited references Yu and Cotsarelis demonstrate differences between mouse and human hair follicle stem cell markers, and "the cellular and molecular characteristics of stem cells in the human follicle could be quite different from those in the rodent". It was unpredictable what would be the cell markers for various different human, rat and mouse hair follicle stem cells, which are multipotent stem cells. It was known in the art that a stem cell expresses various different specific cell markers, which specifically defines said stem cells. It is apparent that cell markers that identify multipotent stem cells or differentiated mammalian cells vary among different multipotent stem cells, different cell types and different mammalian species, and even vary among different cell lines. The specification only discloses cell markers for the identification of osteoblasts and adipocytes but

fails to provide adequate guidance for how to identify the vast number of multipotent stem cells, various cell types, and cells derived from tens of thousands of different mammalian species. The claims only recite contacting a mammalian cell with a test compound but it is unclear whether the mammalian cell is dedifferentiated into its corresponding multipotent stem cell or not and it is unclear what kind of multipotent stem cell would be induced by said test compound. Absent specific guidance, one skilled in the art at the time of the invention would not know how to identify compounds that induce dedifferentiation of various lineage committed mammalian cells into numerous different multipotent stem cells. The claims also encompass using numerous different test compounds but the specification fails to provide adequate guidance and evidence for what kind of multipotent stem cells can be induced by those various test compounds. The test compounds have diverse functions and effects on different mammalian cell types and it is unclear what kind of multipotent stem cells can be induced from various mammalian cells derived from numerous different mammalian species. The specification also fails to provide specific guidance for the differentiation media required for various multipotent stem cells to differentiate into various cell types.

Applicants argue that the test compound dedifferentiates the lineage committed mammalian cells into multipotent stem cells and said multipotent stem cells are differentiated into a variety of different lineage committed cell types. Therefore, the test compound is a "dedifferentiating compound" (amendment, p. 9-10). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 3-13-09. The claims recite contacting a mammalian cell with a test compound and then culturing said cells in a first cell culture media and a second cell culture media to differentiate the cells into first and second cell type. There is

no step of removing the test compound and it is unclear what kind of differentiation factors are added in the "first cell culture media" and "second cell culture media". Thus, it appears that the test compound is the compound that induces differentiation of multipotent stem cell into a first and a second cell type, therefore, the test compound should be a "differentiation" compound rather than a "dedifferentiation" compound. It is unclear how a test compound that induce differentiation of multipotent stem cell into differentiated mammalian cell can be considered a compound that induce dedifferentiation of lineage committed mammalian cells into multipotent stem cells. Thus, the claims are not enabled to identify compounds that induce dedifferentiation of lineage committed mammalian cells into multipotent stem cells as claimed.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 9-14-09 was filed after the mailing date of the first Official action on 3-13-09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Conclusion

No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Shin-Lin Chen, Ph.D.
/Shin-Lin Chen/
Primary Examiner, Art Unit 1632